

REMARKS

Claims 12-14 and 23-33 are pending and rejected.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 12-14 and 23-33 are rejected under 35 USC 112 ¶¶ 1 and 2.

Applicants respectfully request reconsideration. Applicants incorporate their previous arguments of record as reasons why they have met their burden under 35 U.S.C. § 112 ¶¶ 1 and 2. Applicants further provide with this Amendment a Declaration under 37 C.F.R. §1.132 from an independent third party skilled in this art (Erlanger Declaration). This Declarant provides examples and analysis of how 35 U.S.C. § 112 ¶¶ 1 and 2 requirements are met.

Compliance with the written description requirement is a question of fact and must be resolved on a case-by-case basis. Compliance with the enablement requirement must determine whether experimentation needed to practice the invention was undue or unreasonable, when considering the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the Inventors, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The Examiner states that the references applicant submitted, as evidence that structures of each of the receptor binding molecules were known to one skilled in the art, was deficient because none supplied the "known or disclosed correlation between function and structure", citing MPEP

§2161II.A.2(a) (Office Action page 3). However, the MPEP requires such a structure/function relationship only "where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function." MPEP § 2163IA.

This is not the case here. The Erlanger Declaration supports applicants' assertion that one skilled in the art does recognize a correlation or relationship between applicants' claimed sulfenate and its claimed function, refuting this basis for rejection. Applicants have provided both the structure (both chemical formula and specific identities of each component), and the function (the chromophore or dye is the photosensitizer, which induces sulfenate radicals, which destroy tissues by necrosis or apoptosis at the receptor to which the sulfenate is located by the receptor binding portion of the compound).

The Examiner requires "the structures of all molecules binding to the somatostatin receptor which would be immediately (emphasis added) pictured by the skilled chemist as required by the MPEP. The word immediately means that no experimentation or trial and error search will suffice to provide the structure of such molecules." (Pages 3-4 of pending Office Action, emphasis in original.) First, the Examiner's standard is factually inaccurate; experimentation must not be "undue", but routine experimentation is permitted. Thus, the Examiner's statement that no experimentation is permitted is not in accord with patent practice. Second, MPEP §2163A requires lack of adequate written description "If the knowledge and level of skill in the art would not permit one

skilled in the art to immediately envision the product claimed from the disclosed process." (emphasis added). The Erlanger Declaration is by a "skilled chemist" who declares that he does immediately envision which molecules would bind to each of these receptors, refuting this basis for rejection.

In determining adequacy of written description, MPEP § 2163IIA1 requires "For Each Claim, Determine What the Claim as a Whole Covers". Applicants reiterate their claimed method of performing a photo procedure which administers the sulfenate to a target tissue. As the Erlanger Declaration has analyzed, this does not require identity of every compound nor does it require calculation of binding affinity, etc. The Examiner has read additional requirements into the claimed method, negating the requirement of MPEP 2163A1.

The Examiner states that "somatostatin receptor binding molecule", "carbohydrate receptor binding molecule" are all indefinite because they are not "art recognized structural terms" (Office Action page 6). The Erlanger Declaration provides evidence that these phrases are sufficiently definite to one skilled in the art, refuting this basis for rejection.

With respect to receptor binding of the sulfenate, the Examiner states that binding affinities and all structures of binding compounds must be checked. The Erlanger Declaration provides evidence that one skilled in the art would know which compounds meet the claimed limitation, rendering the claims sufficiently definite, refuting this basis for rejection.

CONCLUSION

For the foregoing reasons, applicants submit that all the rejections have been overcome and that the application is in complete condition for allowance.

Applicants do not believe any fee is due with this submission. Should any fee or surcharge be deemed necessary, the Examiner is authorized to charge fees or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to telephone applicants' undersigned representative if there are any questions.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

By Beverly A. Lyman
Beverly A. Lyman
Reg. No. 41,961

2700 Carew Tower
441 Vine Street
Cincinnati, Ohio 45202
513 241 2324
513 421 7269 facsimile